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Date: <u>17 March 2004</u>	Name: <u>Mark W. Giamonte</u>	Signature: <u>[Handwritten Signature]</u>

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Edward L. Carver)
Serial No.: 09/198,004) Confirmation No. 1963
Filing Date: November 23, 1998) Art Unit: 1743
For: APPARATUS AND METHOD FOR MIXING FLUIDS FOR ANALYSIS) Examiner: Lyle Alexander
) Docket No. 116310.0032

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO OFFICE ACTION UNDER RULE 116

Dear Sir:

Applicant submits this Response to the outstanding final Office Action received in connection with the above-identified application. Claims 1, 3-6, 31 and 33-47 are pending in this application. All claims stand rejected under 35 U.S.C. § 102(b) as being anticipated by EP 0107333 ("EP '333"), under 35 U.S.C. § 102(e) as being anticipated by Carver et al. (U.S. Patent No. 5,380,491), and under 35 U.S.C. § 102(b) as being anticipated by Yamamoto et al. (U.S. Patent No. 4,030,888). The Examiner's grounds for rejection are hereinafter traversed, and reconsideration is respectfully requested.

It is respectfully submitted that the Examiner has not correctly interpreted the claim language in accordance with the plain and ordinary meanings of the words used. Independent claim 1 recites "means for combining at least one reagent-mixture component stream into a stream of at least one other reagent-mixture component stream for mixing the plurality of reagent-mixture components into a combined reagent-mixture stream". (Emphasis added). The ordinary meaning

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of "combining" is "To join (two or more substances) to make a single substance, such as a chemical compound; mix." (The American Heritage® Dictionary of the English Language, Fourth Edition Copyright © 2000 by Houghton Mifflin Company). The ordinary meaning of "stream" is "A steady current of a fluid." (Id.) And the ordinary meaning of "mixing" is "To combine or blend into one mass or mixture." (Id.) Thus, the ordinary meaning of the recited function is to combine (or join or mix to make a single substance or compound) at least one reagent-mixture component stream (i.e., a steady current of fluid) into a stream of at least one other reagent-mixture component for mixing (i.e., to combine or blend into one mass or mixture) the plurality of reagent-mixture components into a combined (i.e., mixed into a single substance or compound) reagent-mixture stream. The present application does not assign any different meanings to these words recited in the claim, but rather uses the words in a manner entirely consistent with their plain and ordinary meanings.

Accordingly, contrary to the statement at page 3 of the Action, it is respectfully submitted that the Applicant's remarks are entirely commensurate in scope with the pending claims.

The undersigned respectfully disagrees with the Examiner's statement at page 3 of the Action that "The instant claim language of mixture is interpreted as a composition of different components, which clearly reads on the taught sheath fluid/blood/reagent mixture." First, the claim language should be interpreted in accordance with the plain and ordinary meanings of the words used as set forth above. Second, the claim does not recite a "composition of different components", and therefore this interpretation may unnecessarily confuse the issue. In any event, a "composition" is defined as "a mixture or compound". (Id.) A "mixture" is defined as "The act or process of mixing . . . ; The condition of being mixed" (Id.) Contrary to the Examiner's assertion at page 3 of the Action, EP '333 does not teach or suggest any such feature. Rather, as

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set forth clearly in Applicant's Response filed August 27, 2003, EP '333 explicitly teaches not to mix the concomitant flows prior to or during analysis.

In addition, the Examiner's statement at page 3 of the Action that the claim language "does not specify anything about the status of the mixture in a flow cell or when the samples are mixed" is not correct. Independent claim 1 recites:

"means for combining at least one reagent-mixture component stream into a stream of at least one other reagent-mixture component stream for mixing the plurality of reagent-mixture components into a combined reagent-mixture stream;" and

"means for at least one of (i) chemically analyzing and (ii) analyzing a particle distribution of the selected reagent mixture of the combined reagent-mixture stream". [Emphasis added].

Thus, the claim necessarily requires that the reagent-mixture component streams first be combined and mixed into the combined reagent-mixture stream. Then, the combined reagent-mixture stream is analyzed in the flow cell or like means. Independent claims 31 and 42 recite commensurate limitations. EP '333, on the other hand, specifically teaches away from these claim limitations. As set forth in detail in Applicant's Response filed August 27, 2003, EP '333 explicitly teaches not to mix the concomitant flows prior to and during analysis within the flow cell. Accordingly, EP '333 teaches away from the combination as properly interpreted and recited in independent claim 1.

Contrary to the Examiner's assertion at pages 3 and 4 of the Action, the quoted passage at pages 4 and 5 of EP '333 does not teach or suggest "a mixture of first and second fluids simultaneously through the flow cell". As set forth above, the plain and ordinary meaning of "mixture" is "The act or process of mixing . . . ; The condition of being mixed" (*Id.*) Neither this passage nor any other in EP '333 teaches mixing the concomitant flows in the sheath stream flow cell. Rather, EP '333 specifically teaches maintaining the sample and sheath fluid in two

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separate unmixed streams that are concentrically located at two different diameters. For example, EP '333 states: "the sheath stream flow cell 12 brings the sample and sheath streams introduced at inlets 26 and 28, respectively together to form a pair of concentric, substantially unmixed streams, with the sample stream at the center." (Page 7, lines 7-12 of EP '333, emphasis added). EP '333 further states: "This forms the concentric sample-sheath liquid streams through the flow cell under precisely controlled and coordinated, readily reproducible conditions of constant, and optimal, sample and sheath liquid stream diameters . . ." (EP '333 at page 14, lines 4-7, emphasis added). Thus, the concentric sample-sheath liquid streams are not mixed prior to or during analysis in the flow cell, but rather are mixed only when discarded as waste in the flow cell outlet. Indeed, the very purpose of maintaining the separate, unmixed streams as taught by EP '333 is to facilitate analysis in the flow cell. It is respectfully submitted that the Examiner must view each prior art reference in its entirety and for its teachings as a whole, and the clear teaching of the EP '333 is away from the presently claimed invention.

Yamamoto et al. show an automatic blood analyzer that is fixed to make the same dilution ratios, with the same volumes of reagent-mixture components for every blood sample. In addition, the fixed reagent mixtures are mixed in typical cuvette-type chambers, such as the chambers 6 and 11 of FIG. 1. Similarly, Carver et al. mix the blood sample with lysing agent A and/or lysing agent B in a typical mixing cuvette 13. In each reference, the samples and lysing agents are poured into and mixed in the cuvettes. There is no teaching or suggestion in either reference of combining one stream (i.e., "a steady current of a fluid") into another stream to create a combined reagent-mixture stream, as recited in the present independent claims. Further, in each cited reference, after the samples and lysing agents are mixed by pouring into the cuvettes, they are poured out of, or pumped out of the cuvettes, and passed through a sensing cell for analysis. Thus, neither Yamamoto et al. nor Carver et al. teach means for combining one reagent-mixture

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component stream into another reagent-mixture component stream and forming a combined reagent-mixture component stream, as recited in independent claim 1. Rather, the reagent mixture components are poured into a cuvette, and mixed within the cuvette, not combined into a combined reagent-mixture stream, as recited in claim 1. The Examiner incorrectly dismisses these clear and unambiguous limitations of the claim at page 4 of the Action on grounds that they recite a "method of intended use" and are of "no patentable moment." As set forth in Applicant's Response filed August 27, 2003, independent claims 1 and 42 recite clear and unambiguous structural limitations that are drafted in "means-plus-function" language under 35 U.S.C. § 112. Accordingly, these recitations must be construed to cover the structure disclosed in the specification for performing the recited functions and equivalent structure. 35 U.S.C. § 112. Thus, the functional recitations in the claims are not merely a "method of intended" use as asserted by the Examiner. Rather, these limitations must be properly construed under § 112, and must be given "patentable moment" in distinguishing over the cited references.

Also with respect to independent method claim 31, there is no teaching or suggestion in the cited references of pumping reagent-mixture streams and combining them into a combined reagent-mixture stream. Rather, in the cited references (Yamamoto and Carver '491), the samples and lysing agents are poured into and mixed in the cuvettes (not pumped in streams that are combined and mixed into a combined reagent-mixture stream), and then after they are mixed, they are poured out of, or pumped out of the cuvettes, and passed through a sensing cell for analysis. Further, the cited references do not teach or suggest -- and the Office Action does not state otherwise -- adjusting the flow rates of the components in accordance with a respective flow-rate ratio of reagent-mixture components forming each selected reagent mixture, as also recited in independent claim 31.

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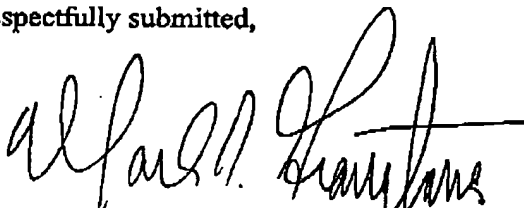
Accordingly, it is respectfully submitted that independent claims 1, 31 and 42 are not anticipated by EP '333, Carver et al. or Yamamoto et al. for at least the reasons set forth above and in the Response filed August 27, 2003. Because dependent claims 3-6, 33-41 and 43-47 each depend from one of these independent claims, it is respectfully submitted that these dependent claims are not anticipated by the cited references for at least the same reasons as the independent claims, and for reciting additional patentable subject matter. Accordingly, all claims are believed to be allowable.

All issues raised by the Examiner having been addressed, an early action to that effect is earnestly solicited.

No fee in addition to that submitted herewith is believed to be required. However, if an additional fee is required, or otherwise if necessary to cover any deficiency in fees already paid, authorization is hereby given to charge our deposit account no. 50-1402.

If the Examiner wishes to discuss any of the issues addressed herein, or otherwise if it would facilitate the examination of this application, he is respectfully requested to call the undersigned at the telephone number below.

Respectfully submitted,

Date: 17 March 2004By 
Mark D. Giarratana (Reg. No. 32,615)
Attorney for Applicants

McCarter & English, LLP
CityPlace I
185 Asylum Street
Hartford, CT 06103
Phone: (860) 275-6719
Fax: (860) 560-5919